

Notice of Allowability

Application No.

10/067,624

Applicant(s)

VALDUCCI, ROBERTO

Examiner

JOHN PAK

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to Applicant's reply of 2/10/2005.
2. ☒ The allowed claim(s) is/are 20, 22-28 [renumbered as 1-8].
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

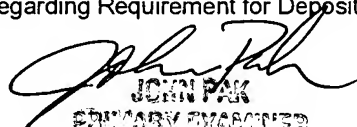
* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____


JOHN PAK
PRIMARY EXAMINER
6/20/07 16:23

This Office action is in reply to applicant's after-final amendments, remarks, and certified translation of the foreign priority document, all of which have been granted entry.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Sapone on February 23, 2005.

Amendments to the Claims

Cancel claims 10-18 and 21.

Claim 20. (Currently amended) A multiparticulate formulation comprising plurality of microgranules or microtablets having dimensions ranging from 200 to 2000 micrometers, wherein each microgranule or microtablet consists essentially of lithium salts and a binder agent and is obtained by granulating the lithium salts with a solution of the binder agent, said plurality of microgranules or micro-tablets being a mixture containing microgranules or microtablets that are coated to have modified release and a remaining portion being uncoated microgranules or microtablets having an unmodified release, said formulation having a lithium salt content of at least 500 mg/g and said

mixture having sufficient modified release coated microgranules or microtablets to have an in vitro dissolution profile suitable for once-a-day administration.

Claim 24, line 4: delete "or" and insert --- and --- .

Claim 26, last line: after the last comma, insert --- and --- .

Claim 28, line 3: delete "conventional" and insert --- unmodified --- .

Amendments to the Specification

Page 1, line 18: delete "tossic" and insert --- toxic --- .

Page 2, line 1: delete "0,4 – 1,2 g / day" and insert --- 0.4 – 1.2 g/day --- .

Page 3, line 27: delete "0,5" and insert --- 0.5 --- .

Page 3, line 31: delete "conventional" and insert --- conventional, unmodified --- .

Page 5, line 18: delete "4,5" and insert --- 4.5 --- .

Page 7, line 9: delete "2,0" and insert --- 2.0 --- .

Page 7, line 10: delete "1,0" and insert --- 1.0 --- .

Page 7, line 11: delete "2,5" and insert --- 2.5 --- .

Page 7, line 12: delete "1,0" and insert --- 1.0 --- .

Page 7, line 23: delete "1,8" and insert --- 1.8 --- .

Page 7, line 32: delete "2,5" and insert --- 2.5 --- .

Page 8, First Table, third line from the top of the page:

delete "14,3" and insert --- 14.3 --- ; and

delete "49,4" and insert --- 49.4 --- .

Page 8, line 11: delete "1,5" and insert --- 1.5 --- .

Page 11, First Table, which appears *immediately after* line 7:

delete "10,4" and insert --- 10.4 --- ;

delete "28,6" and insert --- 28.6 --- ;

delete "53,2" and insert --- 53.2 --- ;

delete "63,7" and insert --- 63.7 --- ;

delete "76,2" and insert --- 76.2 --- ; and

delete "82,3" and insert --- 82.3 --- .

US Patent Application Publication 2004/0241252 is cited to further show the state of the art.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**. The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

Art Unit: 1616

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



JOHN PAK
PRIMARY EXAMINER
CIRCUT 1616